UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC., Plaintiff, v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, Defendant.	Case No.: 10-CV-02037-LHK ORDER DENYING U PENN'S MOTION FOR SUMMARY ADJUDICATION; AND DENYING GENENTECH'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Genentech, Inc. ("Genentech") brings this suit against Defendant Trustees of the University of Pennsylvania ("U Penn") seeking a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 6,733,752 (the "'752 patent"). By counterclaim, U Penn asserts infringement by Genentech. The Court issued an Order Construing Disputed Claim Terms in the '752 Patent on May 9, 2011. *See* ECF No. 214 ("*Markman* Order"). Now before the Court are two motions: (1) U Penn's Motion for Summary Adjudication of Undisputed Material Facts, ECF No. 469 ("Penn MSA"), and (2) Genentech's Motion for Summary Judgment, ECF No. 509 ("Genentech MSJ"). The Court held a hearing on both motions on April 19, 2012. Having considered the submissions of the parties and the relevant law, and for the reasons discussed herein, U Penn's Motion for Summary Adjudication is DENIED, and Genentech's Motion for Summary Judgment is DENIED.

I. BACKGROUND

A. The '752 Patent

The technology at issue is a method of adjuvant cancer therapy using antibodies to prevent a form of breast cancer characterized by the overexpression of HER2 receptors, also referred to as p185. The '752 patent, entitled "Prevention of Tumors with Monoclonal Antibodies Against Neu," was issued on May 11, 2004 and has a presumptive priority date of March 30, 1994.[1] The '752 patent describes antibodies to the protein expressed by the *neu* oncogene. '752 Patent 1:34-39. The *neu* oncogene codes for a cell surface receptor protein named p185, referred to in humans as HER2. *Id.* Amplification of the *neu* oncogene (and resulting overexpression of p185) has been linked to certain types of cancers, including breast cancer. *Id.* at 1:40-53; 2:45-55. The '752 patent discloses a method for preventing transformation of a breast cell that overexpresses p185 into a cancer cell by treatment with anti-p185 antibodies. These antibodies specifically bind to p185 on the cell surface, and thereby "interfer[e]" with the transformation of the cell into a cancer cell. *Id.* at 2:32-38.

In Example 1, the '752 inventors describe production of anti-p185 mouse antibodies. *Id.* at 4:51-6:60. One of the resulting antibodies was named 7.16.4. *Id.* Cells producing this antibody were deposited in the American Type Culture Collection (ATCC) as accession number HB 10493. *Id.* In Example 2, the inventors of the '752 patent describe an experiment using transgenic mice that overexpress a rat *neu* oncogene ("Bouchard" mice). *Id.* at 6:62-7:14. The Bouchard mice develop breast tumors at about 40 weeks of age. *Id.* The inventors treated the Bouchard mice with low and high doses of the 7.16.4 antibodies, and reported that the high dose of antibody suppressed tumor formation in half the mice. *Id.* at 7:65-8:12.

B. Accused Instrumentalities

Genentech is a biotechnology company that manufactures the FDA-approved drug Herceptin (active ingredient trastuzumab). Herceptin is a humanized monoclonal antibody for the treatment of a form of breast cancer characterized by the overexpression of HER2 receptors.

[1] The '752 Patent claims priority to a Patent Cooperation Treaty (PCT) application, number 08/525,800, filed March 30, 1994. The priority date is not in dispute in the parties' motions.

Although Herceptin has an indication as a first-line treatment for metastatic breast cancer, the instant litigation concerns the method of administering Herceptin as indicated for adjuvant treatment to reduce the risk of cancer recurrence in patients who have been diagnosed with primary breast cancer and who have been treated by surgical removal of their breast tumor(s) ("resection") (the "Adjuvant Population"). *See* Decl. of Jason Sheasby in Supp. of U Penn's MSJ, ECF No. 438 ("Sheasby Decl."), Ex. 1 [Penn's 3d Am. Infringement Contentions], at 2.

The FDA-approved package insert for Herceptin ("Herceptin Label") instructs that "Herceptin is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature . . .) breast cancer [a] as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel[; b] with docetaxel and carboplatin[; or c] as a single agent following multi-modality anthracycline based therapy." Sheasby Decl. Ex. 4 [Herceptin Label], at 2.[2] A recent study in 2011, funded by Genentech's parent company, Roche, tested the efficacy of trastuzumab in clearing HER2/neu-positive ITC from the bone marrow of patients completing primary treatment, and concluded that trastuzumab is effective in clearing HER2+ ITCs from bone marrow during recurrence-free follow-up in breast cancer patients. Sheasby Decl. Ex. 41 [Rack et al., "Trastuzumab clears HER2/neu-positive isolated tumor cells from bone marrow in primary breast cancer patients," June 30, 2011 ("Rack 2011")]. U Penn submits that administration of Herceptin to patients who have had HER2+ primary breast tumors removed, in accordance with the "Adjuvant Treatment, Breast Cancer" indications of the Herceptin Label, directly infringes the '752 patent because Herceptin acts on p185-overexpressing isolated tumor cells ("ITCs") that are not "breast cancer cells" within the meaning of the '752 patent, and prevents their transformation into cancer cells. To the extent Genentech induces health care providers to administer Herceptin in a manner that directly infringes the '752 patent, through Genentech's provision of Herceptin, its FDA-approved Herceptin Label, and its marketing, advertising, detailing, training, studies, presentations, publications, and

[2] While Herceptin's FDA-approved label serves as the primary basis for U Penn's infringement contentions, U Penn has also adduced surveys of medical practitioners as additional evidence.

demonstrations on Herceptin, U Penn seeks to hold Genentech liable for indirect infringement under 35 U.S.C. § 271(b).

C. Claim Construction Order

After holding a technology tutorial and claim construction hearing, the Court issued an order on May 9, 2011, construing eight disputed claim terms in the '752 Patent. *See* ECF No. 214 ("*Markman* Order"). Of those eight terms, only three – all appearing only in independent claim 1 of the '752 Patent – are of particular relevance to the parties' cross-motions now before the Court: (1) "breast cancer cells;" (2) "breast cells that overexpress p185;" and (3) "an individual in need of such inhibition." Claim 1 recites:

> A method of inhibiting development into **breast cancer cells** of **breast cells that overexpress p185** in **an individual in need of such inhibition** which comprises administering to said individual an antibody which competes with an antibody produced by cell line ATCC Deposit No. 10493 for binding to p185 and specifically binds to p185 in sufficient amount to down regulate the overexpressed p185 and inhibit the development of said breast cells that overexpress p185 into breast cancer cells.

'752 Patent 8:49-57 (emphases added).

1. "breast cancer cells"

The Court construed the term "breast cancer cells" to mean "**cells from the breast that have malignant form and structure, the ability for uncontrolled growth, and the potential or ability to invade or metastasize**." *Markman* Order at 10. In reaching this construction, the Court considered the various limitations proposed by the parties. U Penn argued that "breast cancer cells are "cells, the origin of which is breast tissue, that have the properties of uncontrolled growth and invasiveness." *Id.* at 4. Genentech argued that the term means "cells from the breast that (a) have malignant form and structure and the potential to invade and metastasize or (b) have invaded or metastasized." *Id.* The Court determined that U Penn's proposal limited the term to only the most advanced forms of invasive tumors without adequate support for doing so, and found that the intrinsic evidence supported Genentech's broader construction, which would include non-invasive tumors such as ductal carcinoma in situ ("DCIS"). The Court further concluded that the ability for

uncontrolled growth is what permits a tumor to form and therefore included that property in the claim construction.

2. "breast cells that overexpress p185"

The Court adopted U Penn's proposed construction of the claim term "breast cells that overexpress p185" and construed the term to mean "**cells, the origin of which is breast tissue, that overexpress p185 and are not breast cancer cells**." *Markman* Order at 12. Genentech advocated for two limitations, both of which the Court rejected. First, Genentech argued that the cells in question must be "normal" because the specification repeatedly states that the invention is directed to preventing "normal cells from transforming into tumor cells." '752 Patent 3:11-12. The Court rejected Genentech's proposal to re-introduce the term "normal" into the claim in light of the fact that U Penn had to remove "normal" from the claims during prosecution of the patent before the PTO. *Markman* Order at 11. Second, Genentech advocated for a locational limitation, arguing that the term should be limited to cells located in the breast. This limitation was rejected as superfluous because neither party introduced evidence of non-cancerous p185-overexpressing breast cells that occur outside the breast. *Id.* at 11-12.

3. "an individual in need of such inhibition"

Finally, the Court construed "an individual in need of such inhibition" to mean "**an individual who (i) has a family history of *neu*-associated breast cancer or a genetic predisposition to *neu*-associated breast cancer but who has not developed *neu*-associated breast cancer; or (ii) has had her/his *neu*-associated breast cancer tumors removed by surgical resection, or has been diagnosed as having *neu*-associated breast cancer enter remission**." *Markman* Order at 15-16. In doing so, the Court rejected Genentech's prosecution argument that U Penn clearly and unmistakably disclaimed the tumor-removal/remission class of patients. *Id.* at 14-15.

II. LEGAL STANDARD

Summary judgment is appropriate if, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party, there are no genuine issues of

material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). At the summary judgment stage, the Court "does not assess credibility or weigh the evidence, but simply determines whether there is a genuine factual issue for trial." *House v. Bell*, 547 U.S. 518, 559-60 (2006). A fact is "material" if it "might affect the outcome of the suit under the governing law," and a dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* (internal citations omitted).

The moving party bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party, but on an issue for which the opposing party will have the burden of proof at trial, the party moving for summary judgment need only point out "that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325; *accord Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, "specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250 (internal quotation marks omitted).

The Federal Circuit has consistently held that the application of a court's claim construction to undisputed facts is a proper subject of summary judgment or summary adjudication. *See, e.g.*, *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1319 (Fed. Cir. 2011). Summary judgment of noninfringement requires a two-step analysis. "First, the claims of the patent must be construed to determine their scope. Second, a determination must be made as to whether the properly construed claims read on the accused device." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999) (internal citations omitted). "[S]ummary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable

to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." *Id.*

III. DISCUSSION

A. Literal Infringement

U Penn alleges that administering Herceptin to the Adjuvant Population according to the procedures set out in the FDA-approved Package Insert for Herceptin (the "Herceptin Label") acts on ITCs and inhibits them from transforming into breast cancer cells, thus satisfying the limitations of claim 1 of the '752 patent. U Penn argues that this practice infringes its method claims and thus seeks summary adjudication of two material facts it claims are undisputed: (1) ITCs are not "breast cancer cells" under the Court's claim construction; and (2) Herceptin can act on ITCs to inhibit them from becoming cancer cells. Penn MSA at 1. Genentech contends that ITCs *are* "breast cancer cells" and therefore seeks summary judgment on the basis of noninfringement. The Court considers each of these two material facts in turn to determine whether a genuine dispute exists.

1. Whether ITCs are Cancer Cells

The central dispute in the parties' cross-motions is whether ITCs in the bone marrow of early-stage breast-cancer patients are "breast cancer cells," and thus not "breast cells that overexpress p185," under the Court's construction of those terms as they are used in the '752 patent. As a preliminary matter, however, the parties fundamentally disagree as to whether this very question is a matter of claim construction for the Court to decide or a matter of infringement for the trier of fact. The Court therefore resolves this threshold dispute before turning to assess the parties' evidence.

a. Question of Law or Fact

Determination of patent infringement involves a two-step process. Claim construction is the first step, wherein the court resolves any disputes regarding the meaning and scope of the claim terms, "and when necessary [explains] what the patentee covered by the claims, for use in the determination of infringement." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). In the second step, the trier of fact must "determine[] whether every claim limitation,

or its equivalent, is found in the accused device." *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1377 (Fed. Cir. 2008) (citation omitted).

Although the Court has already construed the term "breast cancer cells," Genentech argues that "[t]he question now before the Court . . . is whether a proper construction of 'breast cancer cells' includes ITCs, as it does DCIS and micrometastases, such that their treatment is outside the scope of the '752 patent." Genentech MSJ at 9. Genentech believes that the Court can resolve the question of infringement purely as a matter of claim construction for two reasons. First, Genentech argues that "[t]his is a question of claim construction that implicates the scope of claim terms the Court has interpreted." Genentech MSJ at 9. Second, Genentech argues that "'[w]here, as here, the parties do not dispute any relevant facts regarding the accused product but disagree over which of two possible meanings of [a claim] is the proper one, the question of literal infringement collapses to one of claim construction and is thus amenable to summary judgment.'" *Id.* (quoting *Athletic Alts., Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996)). Genentech contends that there is no dispute here about what Herceptin does and thus no dispute about the "accused product"; rather, the dispute is about whether ITCs fall within the scope of Claim 1 of the '752 patent.

The Court disagrees on both counts. First, the Court has already construed the term "breast cancer cells" to mean "cells from the breast that have malignant form and structure, the ability for uncontrolled growth, and the potential or ability to invade or metastasize." *Markman* Order at 10. Thus, the scope of the claim term is clear and is not erroneously left for the jury to decide. *Cf. O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008) (where parties dispute the scope of claim terms, courts have a duty to construe the terms). Genentech does not seek clarification of any of the terms used in the Court's construction of "breast cancer cells." *Cf. Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1384 (Fed. Cir. 2009) (district court did not err by interpreting the party's proposed construction). Nor does Genentech advocate for a different construction of the term "breast cancer cells" based on newly introduced evidence of what was known about ITCs in 1994. For example, if Genentech were

arguing that persons of ordinary skill in the art in 1994 considered ITCs to be cancer cells *and* that it was known in 1994 that ITCs lack the ability for uncontrolled growth, then Genentech would have a reasonable basis for asking the Court to excise the "ability for uncontrolled growth" limitation of its construction of the term "breast cancer cell." But that is not what Genentech argues now. Instead, Genentech simply argues that the construction the Court has already adopted necessarily encompasses ITCs because ITCs were thought to be micrometastases, which were thought to be cancer cells, at the time of the invention. In construing the term "breast cancer cells" during the *Markman* proceedings, however, the Court already considered the known properties of micrometastases, which include the "ability for uncontrolled growth." *See Markman* Order at 12. Thus, the Court is not persuaded that it must re-construe "breast cancer cells" in order to account for ITCs.

Second, while claim construction involves determining the scope of the claim terms as a matter of law, it is decidedly not the task of the court to determine whether every accused product falls within the "scope" of the terms once the terms are construed. A court may not, "under the rubric of claim construction, [] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998). Were it otherwise, "all questions of infringement [would] collapse into questions of claim construction." Penn Opp'n at 9. The Federal Circuit has explained that the infringement question collapses into one of claim construction only where the parties agree that the accused product infringes under one claim construction and that the accused product does not infringe under an alternative claim construction. *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1302 (Fed. Cir. 2011). Here, however, as in *Uniloc*, "the claim construction itself is not contested, but the application of that claim construction to the accused device is." *Id.* While ITCs themselves are not the accused infringing

product, the administration of Herceptin to patients who have HER2+ ITCs in the bone marrow is the accused infringing method. Thus, to the extent the parties disagree on the properties of ITCs as understood today, the Court finds that there is a dispute over relevant facts concerning the accused method. The Court therefore agrees with U Penn that this is a factual question of infringement, i.e., a question of "whether the construed claim reads on the accused product." *PPG Indus.*, 156 F.3d at 1355; *see, e.g.*, *Biotec Biologische Naturverpackungen GmbH & Co. KB v. Biocorp., Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001) (upholding district court's determination that disputed issue was the proper application of a claim term to an accused process rather than the scope of the term itself).

In any event, even if the Court were to consider the properties of ITCs as understood by persons of ordinary skill in the art in 1994 as part of claim construction, doing so would not obviate the independent factual inquiry into whether ITCs, as understood today, possess the properties of a "breast cancer cell" as used in the '752 patent. "[A]s is well established, an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). Federal Circuit case law clearly "allows for after-arising technology to be captured within the literal scope of valid claims that are drafted broadly enough," and thus even if ITCs were thought to have the ability for uncontrolled growth in 1994, such would not preclude a method that acts on HER2+ ITCs from infringing the claims now, if it is now understood that ITCs do not meet the definition of a "breast cancer cell" as defined within the '752 patent. *See id.* at 1371-72; *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 878-80 (Fed. Cir. 2004) (finding that the claim limitation "regularly received television signal" was broad enough to encompass digital signals even though televisions that could receive digital signals did not exist as of the filing date).

Had the '752 patent claimed a method for inhibiting development of "ITCs" or "micrometastases," the scope of the claimed invention would be locked in and limited to the understanding of the term "ITCs" or "micrometastases" by one skilled in the art at the time of the

invention. The actual claims of the '752 patent, however, do not include any mention of ITCs, micrometastases, or other specific cell types. To the contrary, the '752 patent claims a method only for inhibiting development of "breast cancer cells," as that term was understood by skilled artisans in 1994. The '752 patent thus employs a term broad enough to encompass or exclude different cell types as the scientific community's understanding of those cell types evolves over time.

In summary, to the extent ITCs were considered cancerous by skilled artisans in 1994, a proper construction of the term "breast cancer cells" might be informed by what skilled artisans in 1994 believed to be the properties of ITCs. Genentech, however, does not advocate for a different construction of "breast cancer cells" than the one adopted in the Court's *Markman* Order, and thus the construction set forth in the *Markman* Order stands. Furthermore, to the extent Penn presents evidence that the modern day scientific understanding of the properties of ITCs is different from what was known about ITCs in 1994, the ultimate infringement question of whether ITCs – as understood today – satisfy the '752 patent's definition of "breast cancer cells" stands separate and apart from the Court's construction of the claim terms.

b. Whether ITCs Have the Ability for Uncontrolled Growth

In contrast to claim construction, "infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1356 (Fed. Cir. 2007). Having construed the claim term "breast cancer cells," the Court now must consider whether the limitations of claim 1 read onto the accused method of administering Herceptin to Adjuvant patients in accordance with the Herceptin Label. Because the parties bring cross-motions for summary adjudication of this material fact, the Court must determine whether the parties' competing evidence creates a genuine dispute as to whether ITCs satisfy the '752 patent definition of breast cancer cells, that is, whether ITCs have: (1) malignant form and structure; (2) the ability for uncontrolled growth; and (3) the potential or ability to invade or metastasize. Because the Court finds a material dispute as to whether ITCs have the ability for uncontrolled growth, as detailed below, Genentech's motion for summary judgment on the basis of

noninfringement is denied, as is U Penn's motion for summary adjudication of this fact, and the Court need not consider whether a genuine issue exists with respect to malignant form and structure, or the potential or ability to invade or metastasize.

The central factual dispute concerns whether ITCs have the ability for uncontrolled growth. Genentech cites several expert declarations in support of its argument that ITCs have the ability for uncontrolled growth because they are, by name, "tumor cells" that have spread from the primary breast tumor. *See* Cote Decl. ¶¶ 33, 87; Pantel Decl. ¶ 26; Park Decl. ¶ 52; Vogel Decl. ¶ 39. Genentech also cites evidence that, as demonstrated by their detection in the bone marrow, these cells have necessarily invaded through the basal lamina of the breast duct and made their way through foreign tissue, thus already exhibiting the ability for uncontrolled growth and invasion. *See, e.g.*, Pantel Decl. ¶¶ 26, 67, 82, 99. Genentech also submits evidence that, even by 1994, it was known that ITCs could give rise to tumors in secondary sites. *See* Pantel Decl. ¶ 37 & Ex. OO (G. Riethmuller et al., "Immunological Analysis of Micrometastases and the Metastatic Phenotype of Human Tumors," 1989], at 1084. Furthermore, Genentech cites to various studies finding a correlation between the presence of ITCs in bone marrow and the increased frequency of cancer relapse after surgery as evidence that ITCs are tumorigenic and therefore have the ability for uncontrolled growth outside the breast. *See, e.g.*, Pantel Decl. ¶¶ 41-43, 84, 96; Cote Decl. ¶¶ 29, 224-26.

U Penn introduces competing expert testimony in support of its argument that ITCs lack the ability for uncontrolled growth. First, U Penn introduces evidence that, although it may have long been presumed that ITCs derive from primary breast tumors, recent studies suggest that ITCs may originate from atypical ductal hyperplasia ("ADH"), which the parties seem to agree is noncancerous. *See* Sheasby Decl. Ex. 56 [Husemann et al., "Systemic Spread Is an Early Step in Breast Cancer," January 2008]. U Penn introduces other evidence that ITCs disseminate very early from the primary tumor and develop separately, exhibiting different chromosomal mutations than the cells of the primary tumor. *See* Aaronson Decl. ¶ 89 & Ex. 29 [Aaronson 1st Rep.], ¶¶ 301-08. U Penn argues that, like ADH cells, ITCs are a type of precancerous cell, and though ITCs may

have a risk of developing into '752 patent breast cancer cells, this risk does not make ITCs themselves cancer cells. Penn MSA at 14-15.

Second, U Penn puts forth evidence that under the "TNM System" for classification of cancer staging, ITCs at distant locations like bone marrow are categorized as noncancerous. *See* Penn MSA at 18. The TNM System, a widely used means for classifying the extent of cancer spread, has been adopted by a world-wide body of national committees. The TNM System is applied to cancer patients who have presented with a primary tumor, such as a breast tumor, and describes the extent of the patient's disease based on three variables: T, the "primary" site; N, presence in "regional lymph node[s];" and M, presence of "distant" metastasis. Sheasby Decl. Ex. 44 [UICC TNM Classification Manual, 7th Ed.], at 7. The TNM system classifies ITCs as M0, meaning cancer is not present at distant cites. *See id.* at 13-15. U Penn argues that, contrary to Genentech's assertion that ITCs and micrometastases exhibit the same properties, ITCs and micrometastases are in fact biologically distinct entities, as evidenced by the fact that ITCs are staged M0, while micrometastases are staged M1 under the TNM system.

Third, U Penn introduces evidence that Genentech's own experts agree that the ability for uncontrolled growth requires several properties, including the cell's ability to grow autonomously, generate its own growth signals, and proliferate without environmental cues. *See* Sheasby Decl. Ex. 39 [Stern Dep.], at 35:5-17; Sheasby Decl. Ex. 22 [Cohen Dep.], at 214:15-215:9. U Penn introduces evidence that Genentech's own expert, Dr. Klaus Pantel, agrees that additional triggers are necessary for ITCs in M0 patients "to develop the ability of uncontrolled growth." Sheasby Decl. Ex. 30 [Pantel Dep.], at 124:24-125:25.

Based on this record, the Court concludes that there is a genuine dispute as to whether ITCs possess the ability for uncontrolled growth. Accordingly, U Penn's motion for summary adjudication of this fact is DENIED, and Genentech's motion for summary judgment on the basis of noninfringement is likewise DENIED.

2. Whether Herceptin "Acts on ITCs to Inhibit them From Becoming Cancer Cells"

U Penn also seeks summary adjudication that "Herceptin can act on ITCs to inhibit them from becoming cancer cells." In support of its motion, U Penn submits evidence that Genentech's senior Herceptin pathologist, Dr. Howard Stern, and Genentech's 30(b)(6) witness on Herceptin's activity on ITCs, Senior Fellow Dr. Robert Cohen, agree that when administered as adjuvant therapy, Herceptin "acts on" ITCs at distant locations to prevent recurrence in the Adjuvant Population. *See, e.g.*, Sheasby Decl. Ex. 39 [Stern Dep.], at 166:15-168:3; Ex. 24 [Cohen II Dep.], at 458:8-459:13; Ex. 22 [Cohen Dep.], at 186:22-187:21. Furthermore, U Penn points to a 2011 study funded by Roche, Genentech's parent company, which reported that "[p]ersistent bone marrow ITC predict an increased risk of relapse and reduced survival'" and concluded that Herceptin "is effective in clearing HER2+ ITCs from bone marrow during recurrence-free follow-up in breast cancer patients." Sheasby Decl. Ex. 41 [Rack 2011].

Although U Penn presents evidence that Herceptin "acts on" ITCs, the Court does not agree that the evidence uncontrovertibly establishes that Herceptin acts on ITCs "to inhibit them from *becoming cancer cells*." To the extent Genentech has raised a genuine issue of material fact regarding whether ITCs are "breast cancer cells," the same genuine dispute precludes the Court from granting summary adjudication on whether Herceptin "acts on ITCs to inhibit them from becoming cancer cells," since this latter fact presumes that ITCs are not already cancer cells. The Court also agrees with Genentech that the phrase "acts on" is not a claim limitation that appears in the '752 patent and is therefore immaterial to proving infringement of the '752 patent. Accordingly, U Penn's motion for summary adjudication of this fact is DENIED.

B. Infringement by Equivalents

U Penn's infringement contentions accuse Herceptin of infringing both literally and under the doctrine of equivalents. "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co, Ltd.*, 535 U.S. 722, 733 (2002). Under this doctrine, "an accused product that differs from the claim, and thus does not literally infringe, nonetheless infringes if its difference from that claim is

insubstantial from the perspective of one of ordinary skill in the relevant art." *Athletic Alts.*, 73 F.3d at 1581 (citation omitted). The doctrine of equivalents, however, "is not a license to ignore or 'erase . . . structural and functional limitations of the claim,' limitations 'on which the public is entitled to rely in avoiding infringement.'" *Id.* at 1582 (quoting *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987)).

"Whether a claim is infringed under the doctrine of equivalents may be decided on summary judgment if no reasonable jury could determine that the limitation and the element at issue are equivalent." *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1317 (Fed. Cir. 1999) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997)). U Penn argues that, because Genentech's motion does not seek summary judgment of U Penn's claim for infringement under the doctrine of equivalents, trial on the question of equivalents is inevitable. Penn Opp'n at 13. Genentech offers no response to U Penn's position. In any event, because the Court finds triable issues of fact on U Penn's literal infringement claim, even if Genentech had moved for summary judgment on this ground, the Court necessarily also finds triable issues of fact on U Penn's claim of infringement by equivalents. Both claims therefore must go to a jury.

C. Inducement

U Penn accuses Genentech of inducing infringement by actively inducing physicians to prescribe the administration of Herceptin to members of the Adjuvant Population for the treatment of HER2+ ITCs in the bone marrow. Genentech asserts that, even if the Court finds genuine issues of fact as to whether administering Herceptin in the adjuvant setting to act on HER2+ ITCs directly infringes the '752 patent, summary judgment should still be granted on U Penn's inducement claim because: (1) U Penn has not put forth sufficient evidence to create a genuine issue of fact as to whether direct infringement occurred; and (2) U Penn has not presented sufficient evidence from which a jury can infer inducement based on Genentech's instructions to physicians.

Patent law provides that "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Unlike a claim for direct infringement, which requires neither scienter nor mens rea, a claim for actively inducing infringement requires both, as recently

confirmed by the Supreme Court. *See Global-Tech Applicances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011). Thus, to prevail on an inducement claim, a patentee must show "first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1353-54 (Fed. Cir. 2008) (internal quotation marks and citation omitted); *accord DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc).

1. Evidence of Direct Infringement

To prove direct infringement, a patentee must either (1) "point to specific instances of direct infringement," or (2) "show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citing *Dynacore Holdings corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1275-76 (Fed. Cir. 2004)). Genentech argues that it is entitled to summary judgment on U Penn's inducement claim because U Penn fails to identify specific instances of direct infringement and because U Penn fails to create a triable issue of fact as to whether Herceptin "necessarily infringes" the '752 patent.

First, Genentech argues that in order for U Penn to show a specific instance of direct infringement under its infringement theory, U Penn "must show that Herceptin administered in the adjuvant setting specifically acts on HER2 overexpressing ITCs to inhibit their development into breast-cancer cells, and not on, for example, HER2 overexpressing micrometastases, which [U Penn] concedes are cancerous." Genentech MSJ at 19. Based on this understanding of what evidence is required to show direct infringement, Genentech argues that "Penn has not attempted to identify any patient in the accused adjuvant population who had ITCs, but not micrometastases, who was administered Herceptin after surgery, and whose ITCs were inhibited from developing into breast-cancer cells." *Id.*

The Court is not persuaded that there is an absence of material dispute as to direct infringement. Assuming resolution of the dispute over whether ITCs are "breast cancer cells" in favor of U Penn, the non-moving party, the Court finds that U Penn has presented direct evidence

that Herceptin is administered, at least in some instances, in an infringing manner. Specifically, U Penn has done so through expert testimony, physician surveys, and clinical studies collectively showing that: (1) HER2 overexpressing ITCs are detected in the bone marrow of approximately 20% to 40% of the Adjuvant Population, *see* Sheasby Decl. Ex. 30 [Pantel Dep.] at 105:11-106:4; (2) Herceptin is administered to the Adjuvant Population to prevent recurrence, *see* Sheasby Decl. Ex. 41 [Rack 2011]; and (3) Herceptin achieves its results via down regulation of the overexpressed p185 receptors on HER2 overexpressing ITCs, as that term has been construed by the Court, i.e., without reliance on ADCC or CDC, *see id.*; Aaronson Decl. ¶¶ 95-103. The Court agrees with U Penn that this evidence is sufficient to establish a triable issue as to whether there were specific instances of direct infringement among the Adjuvant Population.

Second, Genentech further argues that U Penn's inducement claim fails as a matter of law because U Penn cannot prove that any use of Herceptin in adjuvant therapy necessarily infringes. An accused product does not "necessarily infringe" if it "can be used at any given time in a noninfringing manner." *ACCO*, 501 F.3d at 1313. Genentech posits that "[b]y sweeping the entire adjuvant population into its infringement claim but admitting that only a minority of that population may possess the cells on which its claimed invention operates to prevent transformation, Penn has accused substantial non-infringing uses of Herceptin." Genentech MSJ at 20-21. However, because U Penn has presented sufficient evidence to create a genuine issue of fact as to whether specific instances of direct infringement exist among the Adjuvant Population, U Penn need not present evidence that use of Herceptin "necessarily infringes" the '752 patent in order to survive summary judgment.

Finally, Genentech argues that U Penn must present evidence "that Herceptin act[s] to 'inhibit the development' of p185 overexpressing ITCs without relying on ADCC or CDC" in order to sufficiently support the direct infringement element of its induced infringement claim for the purposes of this Motion. Genentech's argument is undermined by the fact that Genentech has withdrawn its noninfringement contention based on the down regulation limitation. *See* Sheasby Opp'n Decl. ¶¶ 51-53. In any event, U Penn submits evidence that Herceptin does, in fact, achieve

its results without relying on ADCC or CDC, which is sufficient to raise a triable issue of fact. *See* Aaronson Decl. ¶¶ 95-103. Accordingly, because U Penn has presented sufficient evidence from which a jury could make a finding of direct infringement, summary judgment on this ground is improper.

2. Knowledge and Intent

In addition to proving direct infringement, U Penn must show knowledge and intent to induce such infringement. "[M]ere knowledge of possible infringement by others does not amount to inducement; [rather,] specific intent and action to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990)). Genentech argues that, even assuming that certain uses of Herceptin can infringe the '752 patent, summary judgment on the inducement claim should be granted in its favor because U Penn has failed to adduce evidence from which a reasonable jury can infer that Genentech possessed the requisite knowledge and intent to induce infringement.

"While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988); *accord AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Genentech argues that U Penn has failed to present direct evidence of intent to induce infringement and that U Penn's circumstantial evidence is insufficient to give rise to a reasonable inference of intent. Genentech argues that it is "undisputedly possible to use the accused [product] as directed without ever practicing the claimed method," *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009), because it is undisputed that Herceptin is administered in the adjuvant setting in several substantial, non-infringing ways, including to treat micrometastases. Genentech MSJ at 19.

Genentech relies on *Warner-Lambert*, in which the Federal Circuit rejected the patentee's arguments that intent to induce infringement could be inferred from the fact that 2.1% of prescriptions written for the accused drug were for an infringing use. 316 F.3d at 1365. The Federal Circuit explained, "[w]here there are many uses for a product, . . . and fewer than 1 in 46

sales of that product are for infringing uses, [the Court is] not in a position to infer or not infer intent on the part [of the accused] without any direct evidence." *Id.* Genentech is correct that "where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the [alleged inducer] has actual knowledge that some users of its product may be infringing the patent." *Id.* "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327 (defining "substantial non-infringing use" in the context of contributory infringement under 35 U.S.C. § 271(c)). Genentech argues that intent to induce infringement cannot be inferred based on the record presented here because Herceptin has substantial noninfringing uses, such as acting on micrometastases, which the Court has already determined are "breast cancer cells" as defined under the '752 patent.

Nevertheless, while actual knowledge of potential infringement may not be sufficient to infer intent to induce infringement where a product also has substantial noninfringing uses, Federal Circuit cases more recent than *Warner-Lambert* have clarified that "liability for active inducement may be found 'where evidence goes beyond a product's characteristics or the knowledge that it may be put to infringing uses, and shows statements or actions directed to promoting infringement.'" *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935 & n.10 (2005) ("*Grokster*")). In other words, even where a product has substantial noninfringing uses, an accused can still be liable for inducement if the patentee establishes the alleged inducer's "'affirmative intent that the product be used to infringe.'" *AstraZeneca*, 633 F.3d at 1059 (quoting *Grokster*, 545 U.S. at 936 (internal quotation marks and citations omitted)). Such affirmative intent can be proven by presenting "'[e]vidence of active steps . . . taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use.'" *Id.* (quoting *Grokster*, 545 U.S. at 936) (internal quotation marks and citations omitted)). In *AstraZeneca*, the Federal Circuit found that intent to induce could be inferred where the accused inducer was on notice that the product's proposed label could cause at least some users to infringe the asserted

method claims by following the label instructions, yet the accused inducer failed to take any action to rectify the label. *AstraZeneca* demonstrates that, to find induced infringement, the Court need not find that the drug label teaches infringement in every instance, so long as "the language . . . would inevitably lead *some* consumers to practice the claimed method." *Id.* at 1060 (emphasis added).

Here, U Penn has presented sufficient evidence from which a jury could infer that Genentech intended to induce infringement of the '752 patent. Specifically, U Penn presents the following evidence of Genentech's "active steps" to encourage direct infringement: (1) Genentech has known of the '752 patent since it was published as an application in 2000, long before it sought approval for Herceptin in the Adjuvant Population, Aaronson Decl. ¶ 112; (2) the Herceptin Label expressly instructs physicians to use Herceptin in the Adjuvant Population, in which HER2+ ITCs are detected in the bone marrow of 20-40%, as acknowledged by Genentech's own experts, *see* Sheasby Decl. Ex. 30 [Pantel Dep.], at 105:21-106:4; Sheasby Decl. Ex. 4 [Herceptin Label], at 2; Aaronson Decl. ¶¶ 113-18; Sharma Decl. ¶¶ 26-33; (3) the Herceptin Label does not state that the drug should be used to act on '752 patent breast cancer cells or should not act on ITCs in the adjuvant setting, though Genentech admits it could attempt to draft the label to exclude ITCs if it wanted to do so, Aaronson Decl. ¶¶ 115, 118; (4) Genentech actively markets Herceptin in the Adjuvant Population to prevent "recurrence" and to keep patients "cancer free" via "anti-signaling," which is understood as teaching action on ITCs by downregulation, Aaronson Decl. ¶¶ 132-34, 98; Sharma Decl. ¶¶ 31-32; (5) Genentech's parent company, Roche, funded a sophisticated molecular biological study of patients establishing that Herceptin acts on p185 overexpressing ITCs, *see* Sheasby Decl. Ex. 41 [Rack 2011]; Aaronson Decl. ¶¶ 127-30; (6) Genentech markets Herceptin based on the TNM System, which classifies ITCs as M0, and which Genentech experts agree means "no detectable cancer cells at distant locations," Sharma Decl. ¶¶ 42, 44, 48-49; and (7) Genentech represents to the public that Herceptin targets malignant and non-malignant tumor cells alike, Aaronson Decl. ¶¶ 85-88.[3]

[3] U Penn has filed an Administrative Motion to File Under Seal Portions of Its Opposition to Genentech's Motion for Summary Judgment and accompanying exhibits, on which the Court will

From these facts, viewed in the light most favorable to U Penn, a jury could find that Genentech knew Herceptin acted on HER2+ ITCs in the Adjuvant Population, that this infringed the '752 patent's method claims, and that Genentech nonetheless continued to encourage this use of Herceptin. This case is therefore distinguishable from *Warner-Lambert*, in which the label did not prescribe using the drug in an infringing manner, and where the proof of actual infringement was relatively minimal (2.1% of prescriptions).[4] *See* 316 F.3d at 1365. Accordingly, Genentech has not shown an absence of a triable fact concerning U Penn's inducement claim, and summary judgment on this claim must therefore be DENIED.

D. Invalidity Based on Inadequate Written Description

Finally, Genentech argues in the alternative that, even if whether the '752 patent covers ITCs is not a matter of claim construction, summary judgment should be granted in Genentech's

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issue a separate ruling. *See* ECF No. 532. To the extent this Order recites any material from U Penn's Opposition that U Penn seeks to file under seal, the Court includes only material whose redaction has not been adequately supported by a showing of compelling reasons. *See Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006).

[4] Genentech moves to strike from the record pursuant to Federal Rule of Evidence 702 portions of the declarations of Drs. Sharma, Aaronson, and Jensen addressing U Penn's arguments that: (1) "more likely than not," all Adjuvant patients have HER2+ ITCs; and (2) Adjuvant patients receive treatment because they have ITCs, not micrometastases. *See* ECF No. 541. Genentech also separately objects to the Second Declaration of Dr. Roy Jensen, ECF No. 544 ("Jensen Decl. II"), submitted by U Penn as an attachment to its Reply in Support of U Penn's MSA, to the extent it opines that ITCs are present throughout the Adjuvant Population, on the ground that this opinion was not disclosed during expert discovery. ECF No. 557. However, the case law on inducement does not require U Penn to demonstrate that the administration of Herceptin in the adjuvant setting infringes in every instance, and thus the Court's ruling on Genentech's summary judgment motion does not depend on U Penn's evidence that all Adjuvant patients "more likely than not" have ITCs, even if those ITCs are not detected. Furthermore, the Court's summary judgment ruling does not depend on U Penn's expert evidence that Herceptin treats ITCs, not micrometastases, because U Penn has introduced other evidence – such as the Rack 2011 study funded by Roche – that Herceptin has been found effective specifically when targeted at ITCs. In short, the Court finds U Penn's evidence that HER2 overexpressing ITCs are detected in the bone marrow of at least 20-40% of Adjuvant patients, combined with U Penn's evidence of Genentech's awareness of the effectiveness of administering Herceptin to Adjuvant patients with HER2 overexpressing ITCs in the bone marrow, sufficient to create a genuine issue of material fact as to inducement. Because the Court's rulings on the pending summary adjudication and summary judgment motions do not rely on the disputed declarations, the Court defers ruling on Genentech's motion to strike and will instead address it along with the parties' other motions *in limine* at the pretrial conference. For the same reasons, the Court need not rule on Genentech's objection to the Second Jensen Declaration.

favor because the asserted claims are invalid due to inadequate written description. To the extent U Penn asserts that the '752 patent covers a method for inhibiting the transformation into cancer cells of non-cancerous p185-overexpressing breast cells outside of the breast, and specifically of ITCs, Genentech contends "there is no evidence that a person of ordinary skill in the art, reading the application that led to the '752 patent, would understand that the applicants possessed a method for treating ITCs." Genentech MSJ at 25. Genentech points to the absence of any mention of ITCs or any other disseminated tumor cell in the patent's specification, and argues that the patent therefore fails to disclose a method for treating such cells. Genentech MSJ at 3. Accordingly, under Genentech's view, the written description of the '752 patent is inadequate, rendering the patent invalid as a matter of law.

The "written description" requirement set forth in 35 U.S.C. § 112 provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). In other words, the written description requirement "is part of the *quid pro quo* of the patent grant" and ensures meaningful disclosure of what the inventor possessed at the time of the invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354 (Fed. Cir. 2010) (en banc).

Because patents are presumed to be valid, the party seeking to invalidate a patent based on inadequate written description bears the burden of showing, by clear and convincing evidence, that the claims lack an adequate written description. *See* 35 U.S.C. § 282; *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Whether the written description requirement is met is typically a fact question for the jury; however, a written description determination "is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for

the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008) (citation omitted). The test for determining the sufficiency of the written description "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. However, "it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that inventor possessed the invention . . . ." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351 (citation omitted). Thus, the question presented is whether the specification of the '752 patent conveys to those skilled in the art that the inventors were in possession of the claimed subject matter on March 30, 1994.

Genentech argues that the '752 patent is invalid for lack of written description because the specification is devoid of any evidence of ITCs and any evidence of non-cancerous p185 overexpressing breast cells outside of the breast. *See* Genentech MSJ at 24. When the specification discloses the invention, the "claims may be no broader than the supporting disclosure . . . ."[5] *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998). Thus, the Federal Circuit has held a patent invalid based on a lack of written description where the specification discloses an invention that is narrower than the claims of the patent. *See, e.g., Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (lack of written description where the specification touted the advantage of a conical shape but the claims imposed no such limitation); *LizardTech*, 424 F.3d at 1345 (lack of written description where the specification described only one embodiment of the invention claimed); *Gentry Gallery*, 134 F.3d at 1480 (lack of written

[5] To the extent Genentech's statement of the law suggests that the test for written description is whether the limitation is an "essential element" of the claimed invention, Federal Circuit case law has clarified that this is not, in fact, the test to be applied to the written description requirement. *Cooper Cameron Corp. v. Kvaerner Oilfield Prods. Inc.*, 291 F.3d 1317, 1322 (Fed. Cir. 2002).

description where the disclosure unambiguously limited the invention beyond the scope of the claims).

On the other hand, "[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *LizardTech*, 424 F.3d at 1345 (citation omitted). Because the patent specification is written for a person skilled in the art, "such a person comes to the patent with the knowledge of what has come before." *Id.* (citation omitted). As such, it is unnecessary to spell out every detail in the invention: "only enough must be included to convince a person of skill in the art that the inventor possessed the invention." *Id.* Thus, the lack of a reference to ITCs or disseminated cells in the '752 patent does not automatically render Claim 1 invalid for lack of written description, absent evidence that the invention was unambiguously narrower than the claims or that a person of ordinary skill in the art at the time of the invention would understand that the description of the invention is narrower than the claims.

Here, the disputed claim language is: "[a] method of inhibiting development into breast cancer cells of breast cells that overexpress p185 . . . ." '752 patent 8:49-50. While it is true that the '752 patent specification neither discusses ITCs nor specifically describes non-cancerous p185 overexpressing breast cells outside of the breast, it is not clear on the face of the specification that the claim terms are unambiguously broader than the disclosed invention (as opposed to a disclosed embodiment). Thus, the Court must look to the evidence identified by the parties to determine whether a reasonable trier of fact could find that U Penn possessed and disclosed the invention that U Penn is now asserting. *See PowerOasis, Inc.*, 522 F.3d at 1307; *Ariad*, 598 F.3d at 1355.

Genentech is correct that evidence of what a person of ordinary skill in the art knew must arise at the time of the filing date in 1994. Evidence regarding what a person of ordinary skill in the art knows now is not legally relevant. *See Ariad*, 598 F.3d at 1355-56. For example, in *Ariad*, the Federal Circuit reversed a jury determination that the patent in suit was not invalid for lack of written description because most of the evidence presented by the patent-holder was "irrelevant to

the question whether the inventors were in possession of the claimed invention as of the 1989 priority date." *Id.* at 1357.

In this case, based on the evidence provided by the parties, there is sufficient evidence from which a reasonable jury could conclude that the inventor possessed and disclosed a method "of inhibiting development into breast cancer cells of breast cells that overexpress p185," where breast cells that overexpress p185 included ITCs. The specification does not limit the term "breast cells that overexpress p185" to cells located in the breast. Indeed, in construing this term, the Court rejected Genentech's argument to include a locational limitation. *See Markman* Order at 12. U Penn has provided expert evidence that by 1994, researchers understood that human p185 overexpressing breast cells could exist both inside and outside of the breast but were not "breast cancer cells." *See* Jensen Decl. ¶¶ 128-72, 324-30. U Penn has further introduced evidence that by 1994, persons of ordinary skill in the art understood that ITCs and micrometastases were biologically distinct entities, and that ITCs lacked the ability for uncontrolled growth. *See* Jensen Decl. ¶¶ 128-72. This evidence suggests that a person of ordinary skill in the art may have understood the invention to apply to ITCs. Although Genentech disputes this evidence, and argues that there is no intrinsic evidence in the '752 patent that the invention applies to disseminated cells, there is sufficient evidence in the record from which a reasonable jury could find in U Penn's favor regarding what a skilled artisan understood the scope of the invention to be at the time of the filing of the patent application.

Construing the evidence in the light most favorable to U Penn, a reasonable jury could find that the '752 patent's disclosure of a "method of inhibiting development into breast cancer cells of breast cells that overexpress p185" conveys to those skilled in the art that the inventor had possession of a method of inhibiting ITCs from developing into breast cancer cells at the time of the invention. Accordingly, Genentech's motion for summary judgment based on inadequate written description is DENIED.

IV. CONCLUSION

For the reasons stated herein, the Court's construction of the disputed claim term "breast cancer cell" remains as set forth in the May 24, 2011 *Markman* Order, ECF No. 241. U Penn's Motion for Summary Adjudication is: (1) DENIED as to the fact that ITCs are breast cancer cells for purposes of the '752 patent; and (2) DENIED as to the fact that Herceptin can act on ITCs to inhibit them from becoming cancer cells. Genentech's Motion for Summary Judgment is DENIED. The pretrial conference remains as set for May 30, 2012, at 2:00 p.m., and trial will begin on June 11, 2012, at 9:00 a.m.

IT IS SO ORDERED.

Dated: May 14, 2012

LUCY H. KOH
United States District Judge